UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 5
230 SOUTH DEARBORN ST.
CHICAGO, ILLINOIS 60604

REPLY TO ATTENTION OF:

5 HSM-TUB 7

July 15, 1991

Jeffrey A. Lybarger, M.D., M.S.
Director, Division of Health Studies
Department of Health & Human Services
Agency for Toxic Substances and Disease Registry
Atlanta, GA 30333

Dear Dr. Lybarger:

I have enclosed the comments from Region V following our review of the biomedical protocol for the ATSDR Multistate Lead Exposure Study. We still have some reservations about the environmental protocol and look forward to receiving the revised protocol in the form of the Quality Assurance Project Plan (QAPjP), so that the study can meet its stringent time schedule.

If you have any questions concerning the Region V comments, please feel free to call me at (312) 886-4904.

Sincerely yours,

Patricia A. Van Leeuwen
Toxicologist
Technical Support Unit

Enclosure
cc Brad Bradley, RPM
Louise Fabinski, ATSDR
Steve Siegel, ORC
Dave Ullrich, Director, WMD

Review of the ATSDR Multistate Lead Exposure Study Protocol

The information provided in the protocol package still leaves a number of questions related to the integration of health and environmental samples unresolved. Our primary concern in Region V is that the timing and extent of the environmental sampling at the Granite City site be adequate to allow meaningful interpretation of the data. We had hoped to see some further delineation of the ASTSDR environmental data requirements in this proposal - i.e., the environmental protocol proposed to collect environmental samples from study participants whose blood lead levels exceeded 25 ug/dl, while U.S.EPA (and I believe ATSDR) consider the level of concern to be 10 ug/dl, etc. It would be appropriate to include major requirements in the overall protocol and not rely on these issues to be addressed in the attachments. The specific comments which follow are based on a review of the document by myself and Brad Bradley, RPM for the site. We have also offered some overall recommendations following the specific comments.

1) Introduction The introduction sets the tone of the protocol and should be strengthened. Existing studies have already established that lead poses a substantial risk to health, and we do not want to downplay the studies that have established this risk. Our understanding of the need for this study is to further define the extent of the risk to residents in these areas and to further examine the parameters which contribute to this risk. To convey this purpose, we recommend adding additional, new opening sentences to the introduction. One possible beginning is "Over the past decade, new information has revealed significant health risks posed by contaminants such as lead and cadmium. Dr. Louis Sullivan, Secretary of the Agency for Health and Human Services, has declared lead poisoning to be the most devasting environmental disease to young children in the country. Recent studies have demonstrated that high concentrations of these contaminants in soil present a risk to human health (Ref. 2,3). However, the extent ---" (add the reports opening sentences.)

Line 9: The phrase "among other things" should be added in this line.

Line 10: "Evidence" would be a better choice of words than "observation". Also in this line, I think you mean: direct contact with soil can inadvertently result in ingestion of contaminated soil (or harmful contaminants), especially in young children".

Delete the entire next sentence since it has been replaced by the new opening sentences.

Line 24: The use of the term "comparable lead exposure studies" may be misleading as the contaminants from mining operations and from smelting operations are not identical in many respects - i.e., chemical form, particle size, bioavailability, etc. Both types of sites are to be included in the study.

2) Page 6, NL/Taracorp site, para.1 The NL/Taracorp site is not restricted to the confines of Granite City, but also includes Madison and Venice, Illinois. Blast furnace operations ceased in 1983, and the Site became an an NPL Site in 1984. The date given on page 7, last line, is correct.

3) Page 6, fourth line from the bottom "1987" should be substituted for "1988".

4) Page 7, lines 3 and 4 Substitute "45 to 14,700 ppm" for "106 to 9,493 ppm", and "725" for "905".

5) Page 7, Groundwater, third line Substitute "contaminants in groundwater downgradient" for "contaminanted groundwater underlying".

6) Page 7, bottom of the page Add the following sentence to the last paragraph on this page: "Since 1983, air lead levels have declined significantly and have been well below the NAAQS level of 1.5 ug/cu.m."

7) Page 13, Data Collection It is not clear in this discussion if the "60 day residency" requirement is to be meet by information provided on the questionnaire or validated using the door-to-door survey to "fix" residency. Also the protocol does not address the fact that blood samples must be taken in a specific time period in order to accurately assess exposure to outdoor soil lead.

8) Page 15, last two sentences Delete "the effects of soil contamination on this group" and replace it with verbage that does not link soil contamination to health effects.

9) Page 22, Data Analysis Plan As I recall from our discussions at Kansas City, it was decided that a weighing factor to correct for sampling fraction was inappropriate, and that all data would be weighted equally.

10) Page 41, Attachment 1 The insertion of "soil" under the heading "exposure pathway" is incorrect. Soil is a medium. The correct exposure pathway is "soil ingestion". Also, is the stated sample size for biological or environmental sampling? The label is not specific.

11) Attachment 4, Enclosure 2 At the NL/Taracorp site, soil lead levels can be seem to occur as concentric rings, whose concentrations change with respect to the smelter (source). Will this sampling strategy be applied to each ring? What then is the total anticipated environmental sample size for this site? If this sampling strategy is meant to apply only to the Kansas and Missour sites, it should be so labeled.

Recommendations I would like to reinterate that serious consideration should be given to the number of environmental samples to be collected at each site. Other blood lead studies currently under way have greatly expanded sampling schemes - I believe the anticipated number of soil samples to be collected at Leadville, Colorado is in the ballpark of 17,000! Leadville is certainly a more complex site, and I am not suggesting that such extensive sampling is necessary at any of the sites under consideration in this study. However, conclusions based on a study that relies on a limited number of data points cannot be expected to be viewed with the same regard as conclusions from studies where the sampling is more complete. The number of variables being considered to impact on the health effects of lead and cadmium in this study would argue for the collection of a more complete data set.